

IMPORTANT: This guidance replaces that on regulations 22 and 23 on pages 44 to 51 of the Guide to the Genetically Modified Organisms (Contained Use) Regulations 2000 and that on Confidentiality and disclosure of notified data in AGCM newsletter no 32 which is no longer valid from 1 January 2005

GENETICALLY MODIFIED ORGANISMS (CONTAINED USE) REGULATIONS 2000

GUIDANCE ON DISCLOSURE OF INFORMATION from 1 January 2005

What is this guidance about?

1. This guidance explains how HSE will deal with disclosure of information under the Genetically Modified Organisms (Contained Use) Regulations 2000 (GMO(CU)) from 1 January 2005. It primarily explains the provisions of the Environmental Information Regulations 2004 (EIR 2004) as they affect the information held by the HSE and the competent authority in respect of the environmental information contained in notifications and in information supplied to HSE in connection with inspections.

2. We must emphasise that we cannot offer advice on the legal interpretation of the provisions in GMO(CU) or EIR 2004. The views expressed in the guidance as to those provisions are those of HSE and the competent authority. It is for the Courts alone to give a definitive view on the interpretation of the provisions in GMO(CU) and EIR 2004.

Summary

- All information held by HSE in connection with notifications and inspections is potentially disclosable (including that which has previously been withheld from the public register or which the competent authority agreed was confidential prior to 1 January 2005).
- A decision on whether to put information on the public register will take place at the time of notification, but information which is withheld from the public register could be disclosed at a later date if it is in the public interest to do so.
- All requests for information will be assessed on a case by case basis and the public interest in withholding the information under one of the exceptions in EIR 2004 weighed against the public interest in disclosing it (the Public Interest Test).
- Notifiers will be consulted before information subject to the exceptions in EIR 2004 is disclosed (this includes information previously withheld or agreed as confidential).

Background

3. GMO(CU)) came into force against a background of the Government's commitment to strengthening the public right of access to information. That commitment has been strengthened by the Freedom of Information Act 2000 (FOI) and the Environmental Information Regulations 2004 (EIR 2004) which came into force on 1 January 2005.

4. There are two ways information held under GMO(CU) can get into the public domain:

- placing it on the public register held under the Regulations; or
- as a result of a request from a member of the public.

5. GMO(CU) worked on the basis that all information notified under the Regulations might be disclosed to the public unless the notifier could justify withholding items from disclosure on certain specified grounds **and** the competent authority^(a) for the Regulations agreed. In the light of the events of September 11 (2001) and enquiries to HSE concerning anthrax, the Genetically Modified Organisms (Contained Use) Regulations 2002 (GMO(CU)2002) made amendments to GMO(CU) which allow the Secretary of State to authorise the withholding of information from the public on the grounds of national security (see separate guidance leaflet [Contained use of genetically modified organisms - excluding information from the public register](#) [**Provide link** www.hse.gov.uk/pubns/indg357.pdf]

6. From 1 January 2005 any request for information which HSE receives in respect of GMOs must be considered under the provisions of FOI. Where the information sought falls within the definition of 'environmental information' given in EIR 2004 the effect of section 39 of FOI is to direct you to the EIR regime. The requirements of FOI and EIR 2004 are broadly similar. There are, however, some differences. For example, environmental information requests need not be in writing, and the public interest test applies to all grounds for refusing a request for environmental information. Most notifications require a human health and an environmental risk assessment. This means that if the request is for information on human health it will be processed under FOI but if the request is for environmental information within the meaning of EIR 2004 the request must be considered under EIR 2004 instead. For guidance on how requests for information are dealt with under FOI see HSE's information on its website at <http://www.hse.gov.uk/foi/index.htm>

7. Any request for disclosure of information supplied under GMO(CU) which is addressed to and held by the Scottish Executive will be dealt with under the Freedom of Information (Scotland) Act 2002 or under the Environment Information (Scotland) Regulations 2004. The Scottish Executive in consultation with HSE will make the decision on disclosure in these cases.

What changes do FOI and EIR 2004 make?

8. FOI and EIR 2004 have a different starting basis from GMO(CU) for the provision of information, namely:

- they provide two related rights - the right to be told whether the information exists and the right to receive the information;
- they impose an obligation on public bodies (including HSE acting on behalf of the competent authority for GMO(CU)) to comply, subject to certain exemptions.

9. Reg 12(1) of EIR 2004 says that the competent authority may refuse to disclose information requested by a member of the public only if one of the exceptions to disclosure given in regs 12(4) and (5) apply **and** the public interest in maintaining the exception outweighs the public interest in disclosing the information. The competent authority is required to exercise a presumption in favour of disclosure.

10. It must be emphasised that under EIR 2004 all information is potentially disclosable (including that which has already been withheld from the public register or which HSE agreed to keep confidential prior to January 2005). Each application for information will be assessed against the exceptions to disclosure given in EIR and the public interest in maintaining the exception outweighing the public interest in disclosing the information.

What information can be withheld from disclosure under EIR 2004?

11. The categories of information the competent authority is allowed to withhold are broadly similar to those under the Environmental Information Regulations 1992 (quoted in regs 22 and 23 of GMO(CU)) which EIR 2004 replaces, namely:

- material still in the course of completion, unfinished documents or incomplete data;
- internal communications within the competent authority or any other public authority;
- international relations, defence, national security or public safety;
- the course of justice, the ability of a person to receive a fair trial or the ability of a public authority to conduct an enquiry of a criminal or disciplinary nature;
- intellectual property rights;
- the confidentiality of the proceedings of HSE, the competent authority or any other public authority;
- the confidentiality of commercial or industrial information where such confidentiality is provided by law to protect a legitimate economic interest;
- the interest of a person who provided the information where that person -
 - was not under, and could not have been put under, any legal obligation to supply it to that or any other public authority;
 - did not supply it in circumstances that the authority holding it, or any other public authority, was entitled to disclose it, but for the requirements of EIR;**and**
 - has not consented to its disclosure; or
- the protection of the environment to which the information relates.

Guidance on the interpretation of these categories is given in the Defra guidance on EIR 2004 at www.defra.gov.uk/corporate/engov/eir/guidance/index.htm

12. Even where a valid exception to disclosure applies, it should still be possible for HSE to give out the major part of the information held. In supplying information to HSE, it would be helpful if the notifier separated out information that may fall within one of the exceptions from that which is disclosable. The notification forms are already designed to achieve this, but notifiers will need to consider the best way to achieve this in risk assessments and information supplied in connection with inspections. The information then can be easily weeded out if HSE considers that an exception can be upheld.

Is personal data affected?

13. Personal data will continue to be protected by the Data Protection Act 1998. Regulation 13 of EIR 2004 provides that where the information requested includes personal data of which the applicant is not the data subject and as respects which either the first or second condition set out in paragraphs (2) or (3) or regulation 13 apply, a

public authority must not disclose the personal data. Whilst protection will automatically be afforded to personal data by the competent authority, it will be helpful if notifications made under GMO(CU) are structured in such a way that any personal information is easily identifiable and removable. The notification forms^(c) developed for use under the Regulations are specifically designed so that personal information is in a separate section that can easily be removed. If the forms (which are voluntary) are not used, you will have to consider how best you can achieve the same effect. It is not necessary to include personal information, such as individuals' names, eg project leader or staff working on the project, in the risk assessment as the competent authority do not require such information as part of the assessment.

What happens when I send in a notification?

14. Under EIR 2004 the decision on whether there are any grounds to refuse disclosure is made at the time a disclosure request is received from a member of the public. However, because the competent authority will proactively make notification information available to the public by putting it on the public register, it will be necessary for that decision to be made on receipt of the notification insofar as the public register is concerned. (If a later request is received for the information the decision will have to be reviewed).

15. The competent authority will consider whether any of the information, which would normally be placed on the public register, should be withheld from disclosure under the provisions of reg 12 of EIR 2004 or the Data Protection Act 1998 and inform the notifier of its decision. (HSE's notification forms are specifically designed so the notifier can inform HSE of any information they believe should be kept confidential and not placed on the public register). Notifiers must bear in mind that all relevant information **must** be submitted in the notification. The competent authority will use it to evaluate the risk.

16. The former ACGM 'confidentiality' guidance set out in detail how the competent authority would regard various types of requests. Given that EIR 2004 is a new piece of legislation which requires each request for information to be dealt with on a case by case basis and no precedents have yet been set, or legal decisions made by the Courts, it would be premature for the competent authority to give similar guidance in respect of what sort of decisions it will make under EIR 2004.

What happens to my risk assessment?

17. When HSE receives your risk assessment the competent authority will use it to help assess your notification. It should be possible to disclose the majority of the information in risk assessments (on request), so notifiers may wish to consider separating sensitive information that might be considered as coming under the exceptions contained in EIR 2004.

What happens to information I give HSE in connection with inspections?

18. The inspector will use the information you give in relation to inspections for the purpose of the inspection and only essential information will be kept by HSE following completion of the inspection and any related actions. It would be helpful to HSE if, in submitting information for inspections, information which you think might be covered by one of the exceptions in EIR is separated so that it can be weeded out if, having applied

the Public Interest Test, HSE considers it should be withheld if the information is requested.

What happens if people ask for information HSE or other parts of the competent authority hold about my business and me?

19. If HSE receives a request for any of the information it holds about you or your business, whether it is information supplied in the original notification, information in the risk assessment or information given in connection with inspections it will consider the request under FOI or EIR 2004 as appropriate on a case by case basis. This assessment has to be made in the light of the situation prevailing at the time the request is made. The presumption is in favour of disclosure and information only being withheld where the public interest in maintaining the exception outweighs the public interest in disclosing the information. The decision may therefore be made that information which was withheld from the public register initially, or which HSE had previously said it would keep confidential, now has to be released under the FOI/EIR legislation. All requests will be dealt with as soon as possible and at any rate within 20 working days from receipt of the request, unless this deadline is extended in line with the timescales given in EIR 2004 and the guidance on those [Regulations \[provide link www.defra.gov.uk/corporate/opengov/eir/guidance/index.htm\]](http://www.defra.gov.uk/corporate/opengov/eir/guidance/index.htm)

20. It should be emphasised that it is for HSE, as holders of the information, to decide whether the information falls within the exceptions to disclosure. It is important therefore to remember that **all information supplied to the competent authority is potentially disclosable, but clearly it is important for the notifier to alert the HSE of their opinion that the information is non-disclosable.** However, this will not mean that information will be disclosed which it would be inappropriate for HSE or the competent authority to pass on. Each request for information will be dealt with separately, so that information withheld on one occasion, may be disclosed on a subsequent occasion if HSE decides that the exception to disclosure is no longer valid in respect of that information. An acceptance of a claim for non-disclosure (including those made prior to 1 January 2005) is therefore subject to review if a request for disclosure is received. The competent authority will, as in all other cases, inform the notifier in advance if a claim for confidentiality agreed originally is to be revoked and the information released as a result of the Public Interest Test.

21. An enquirer will be told where to locate information if it is already in the public domain ie public register or published in an accessible form.

22. HSE or the competent authority cannot give information if it does not hold the information when an applicant's request is received

23. In all cases of refusal to disclose information, HSE will respond in writing to the applicant specifying the reason why it is not disclosing the information. This reason will include the exception it is withheld under in the relevant legislation ie FOI or EIR 2004; and how HSE or the competent authority has reached its decision with respect to the public interest. The only exception to this information will be in cases of national security where HSE or the competent authority may respond to the request by neither confirming nor denying that it holds the information.

24. If the refusal to disclose information is because the information requested relates to material which is still in the course of completion, unfinished documents or incomplete

data, HSE or the competent authority will let the applicant know the name of any other public authority which is preparing the information (if known) (this is assuming there is one) and the estimated time in which the information will be finished or completed.

What happens about information which the Secretary of State has said will be withheld from the public register?

25. All information is potentially disclosable under FOI/EIR 2004, so HSE will treat the request on the same basis as any other request and apply the Public Interest Test.

What happens about information which HSE has said it will keep confidential prior to 1 January 2005?

26. HSE already holds a lot of information which notifiers have provided in confidence in connection with notifications and inspections. Where a request for this information is received under EIR 2004, HSE will consider whether any of the exceptions in EIR apply and consult the notifier and seek legal advice as necessary before releasing any information.

What happens if a request for information is refused and the applicant wishes to appeal?

27. If an applicant considers HSE has refused information incorrectly or failed to deal with his/her request correctly, they have a right of appeal [**provide link** www.hse.gov.uk/foi/appeals.htm]. In the first instance they should write to:

The Freedom of Information Unit
Room 001
Magdalen House
Stanley Precinct
Trinity Road
Bootle
Merseyside L20 3QZ

28. If they are still not satisfied then they have a right to appeal firstly to the Information Commissioner and then to the Information Tribunal. For details of these procedures see the FOI website at www.foi.gov.uk

Where can I find further information?

29. Guidance on the working of EIR 2004 is given at the Defra website at www.defra.gov.uk/corporate/opengov/eir/guidance/index.htm

Guidance on the working of FOI is given on the HSE website at www.hse.gov.uk/foi/ and the Department for Constitutional Affairs website at www.dca.gov.uk/rights/dca/foidcaintro.htm

30. Copies of the public register held under the Genetically Modified Organisms (Contained Use) Regulations 2000 are held at:

Health and Safety Executive
Biological Agents and GMOs Policy Unit

Rose Court
2 Southwark Bridge
London SE1 9HS
Tel: 020 7717 6348

Health and Safety Executive
HID SI4 Biological Agents
Magdalen House
Stanley Precinct
Bootle
Merseyside L20 3QZ
Tel: 0151 951 4772

31. Registers containing those entries relevant to the locality are held in main HSE offices. (Addresses may be found in the telephone book.) (The Health and Safety Commission has consulted on whether the regional versions of the public register should be withdrawn, see Consultative Document^(b) at www.hse.gov.uk/consult/index.htm)

32. The public register for Scotland is held at:

Health and Safety Executive
Belford House
59 Belford Road
Edinburgh EH4 3UE
Tel: 0131 247 2000
Fax: 0131 247 2121

33. The public register for Wales is held at:

Health and Safety Executive
FOI and Disclosure
Government Buildings
Ty Glas
Llanishen
Cardiff
Wales
CF14 5SH

34. Registers are open to inspection by members of the public during normal office hours, but those wishing to inspect them are advised to telephone first.

35. Contact for anyone wishing to obtain information about notifications, including requests for the risk assessment and any other information not on the public register:

Health and Safety Executive
HID SI4
Magdalen House
Stanley Precinct
Bootle
Merseyside L20 3QZ
Tel: 0151 951 4772

Fax: 0151 951 3474

36. If you have any views on this guidance please send them to gmconsultation@hse.gsi.gov.uk

Notes

(a) The competent authority for England and Wales is the Health and Safety Executive (HSE) and the Secretary of State (Defra). For Scotland the competent authority is HSE and the Scottish Ministers.

(b) CD201 'Proposals for the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005' available from Biological Agents and GMOs Policy Unit, HSE, Rose Court, 2 Southwark Bridge, London SE1 9HS, tel 020 7717 6358, fax 020 7717 6680.

(c) People do not have to use the forms, but the guidance should read across to whatever approach is taken to supplying the information required in a notification.